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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/009,477 | 12/11/2001 | Masahiro Imoto | 1830/50521 | 4095 |

23911 7590 12/03/2004

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EXAMINER

RAO, DEEPAK R

ART UNIT PAPER NUMBER

1624

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,477

Applicant(s)

IMOTO ET AL.

Examiner

Deepak Rao

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35, 36 and 41-59 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) 59 ~~is/are~~ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 ~~is/are~~ is/are allowed.
- 6) ☒ Claim(s) 35 and 41-58 ~~is/are~~ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 16, 2004 has been entered.

Claims 35-36 and 41-59 are pending in this application.

Election/Restriction

Applicant elected the species of Compound No. 2 (page 29, Table 1). The species represents a compound of formula (I) wherein A^1 and R^7-R^{12} are hydrogen and A^2 is 6-chloro-pyrid-3-yl. The elected species was not found in the prior art and the search was expanded (as per the guidelines of MPEP § 803.02) to the compounds of formula (I) wherein X is $-CH_2-CH_2-CH_2-$; A^1 is H, phenyl, alkyl, alkyl substituted with phenyl; and A^2 is optionally substituted phenyl and art was found.

Claim 59 and the subject matter of compounds of formula (I) other than the above indicated subgenus are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35 and 41-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 recites the limitation " an optionally substituted alkyl group, excluding dichloronitromethyl " in lines 5-6. There is insufficient antecedent basis for this limitation in the claim because the substituent list for the 'alkyl group' does not include 'chloro' and 'nitro' and therefore, the above recited group "dichloronitromethyl" can not be excluded (groups that are not included in the claim can not be excluded).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

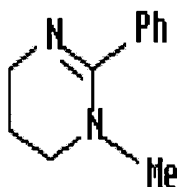
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 36 is rejected under 35 U.S.C. 102(b) as being anticipated by CAPLUS Abstract 101:181274 (1984). The instant claim reads on reference disclosed compound, see compound having RN 92506-20-2 (depicted below for convenience):

RN 92506-20-2 CAPLUS

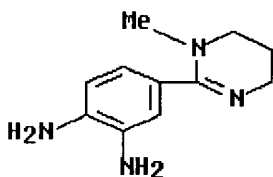
CN Pyrimidine, 1,4,5,6-tetrahydro-1-methyl-2-phenyl- (9CI) (CA INDEX NAME)

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2. Claims 36 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Roesner et al., U.S. Patent No. 4,156,778. The instant claims read on reference disclosed compound, see the compound 2-(3,4-diaminophenyl)-2-tetrahydropyrimidine hydrochloride (col. 7, lines 57-58) (depicted below for convenience):

CN 1,2-Benzenediamine, 4-(1,4,5,6-tetrahydro-1-methyl-2-pyrimidinyl)-, monohydrochloride



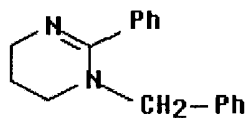
• HCl

3. Claims 36, 41, 46-49 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Brimblecombe et al., CAPLUS 72:41409 (1970). The instant claims read on reference disclosed compounds, see the compound disclosed in the enclosed abstract, particularly those having 2-phenyl substituent (depicted below for convenience):

RN 26148-94-7 CAPLUS

CN Pyrimidine, 1-benzyl-1,4,5,6-tetrahydro-2-phenyl-, hydrochloride (8CI) (CA INDEX NAME)

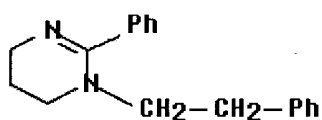
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●x HCl

RN 26148-95-8 CAPLUS

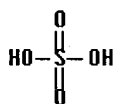
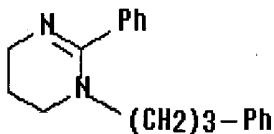
CN Pyrimidine, 1,4,5,6-tetrahydro-1-phenethyl-2-phenyl-, hydrochloride (8CI) (CA INDEX NAME)



●x HCl

RN 26148-99-2 CAPLUS

CN Pyrimidine, 1,4,5,6-tetrahydro-2-phenyl-1-(3-phenylpropyl)-, sulfate (8CI)



4. Claims 36 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by GB

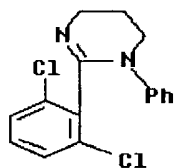
1,013,441. The instant claims read on reference disclosed compounds, see the compound

disclosed page 9, EXAMPLE III (depicted below for convenience):

RN 3797-96-4 CAPLUS

CN Pyrimidine, 2-(2,6-dichlorophenyl)-1,4,5,6-tetrahydro-1-phenyl-,
monohydrobromide

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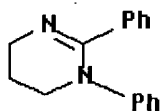


• HBr

5. Claims 36 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Riverdito et al., CAPLUS 115:8219 (1991). The instant claims read on reference disclosed compounds, see the compounds disclosed in the enclosed abstract (depicted below for convenience):

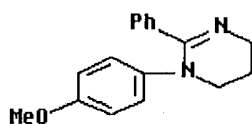
RN 52289-23-3 CAPLUS

CN Pyrimidine, 1,4,5,6-tetrahydro-1,2-diphenyl- (9CI) (CA INDEX NAME)



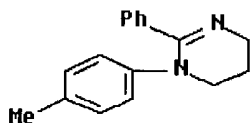
RN 52289-26-6 CAPLUS

CN Pyrimidine, 1,4,5,6-tetrahydro-1-(4-methoxyphenyl)-2-phenyl- (9CI) (CA INDEX NAME)



RN 52289-28-8 CAPLUS

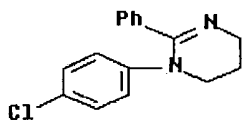
CN Pyrimidine, 1,4,5,6-tetrahydro-1-(4-methylphenyl)-2-phenyl- (9CI) (CA INDEX NAME)



RN 52289-36-8 CAPLUS

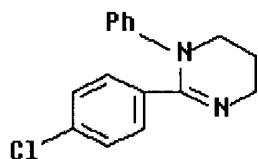
CN Pyrimidine, 1-(4-chlorophenyl)-1,4,5,6-tetrahydro-2-phenyl- (9CI) (CA INDEX NAME)

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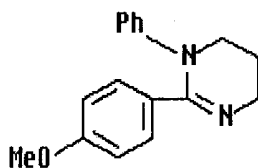
RN 52289-27-7 CAPLUS

CN Pyrimidine, 2-(4-chlorophenyl)-1,4,5,6-tetrahydro-1-phenyl- (9CI) (CA INDEX NAME)



RN 134221-87-7 CAPLUS

CN Pyrimidine, 1,4,5,6-tetrahydro-2-(4-methoxyphenyl)-1-phenyl- (9CI) (CA INDEX NAME)



Note: The above references are representative of the searched subgenus. Claim 35 is extremely broad and covers many known compounds, e.g., **1,4,5,6-tetrahydropyrimidine**, which is available in Aldrich Catalog 29,333-4.

Allowable Subject Matter

Claim 36 is allowed. The references of record do not teach or fairly suggest the claimed compounds.

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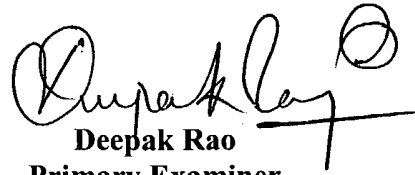
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deepak Rao
Primary Examiner
Art Unit 1624

November 29, 2004